INSTRUCTIONS FOR USE

These Use Instructions refer to all products under registration number

80455630006

Technical Name: Intersomatic Spacing Device of Diskal Substitution.

Commercial Name: TRAUMEC Mono-Portal Lumbar Intersomatic Spacer

WARNING: Read carefully all the instructions before use. Follow all the warnings and precautions mentioned in this instruction. Failure to observe these points may compromise safety and the product efficiency.

Intersomatic Spacing Device of Diskal Substitution

Detailed Description of Medical Product

The Intersomatic Spacing Device of Diskal Substitution are small implants, made of titanium alloy. These spacers are often used to restore the lost height due to compromised disk and/or to relieve the pressure on the root. The Intersomatic Spacing Devices of Diskal Substitution have inner space to be filled with bone graft between the two vertebrae in order to facilitate the fusion between them (arthrodesis), which increases the stability of the system over the term.

The implants may be filled with any bone graft, and such a choice is under the responsibility of the surgeon. This bone graft start to grow through rips in the upper and lower extremities of TRAUMEC Intersomatic Spacing Device of Diskal Substitution. It forms a solid bone (merger) that starts to fix the vertebrae. This process is known as intervertebral merger.

The TRAUMEC Intersomatic Spacing Device of Diskal Substitution is an implantable medical product of modular design, anatomic to the bone, aiming to provide sable biomechanics structure to the lumbar spine to facilitate arthrodesis (vertebral merger). These implants are recommended for inter somatic lumbar arthrodesis via posterior and in case of degenerative disk disease.

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The implants have curvilinear geometric shape, similar to the shape of a bow, with oblongs bystanders, with upper and lower extremities formed by serrated surface that will improve that implant fixation, avoiding its migration. In addition, in lateral contours they have holes that will receive bone graft.

Mechanical polishing finishes the implants, and then this product goes through a process called pickling, which consists of a chemical attack of the polished surface of the metal, removing residual impurities from the manufacturing process, such as: Oils, greases and other materials of manufacture

Next, this product goes through an ionization process, in other words, superficial treatment to reinforce the superficial layer of the products made out of titanium.

TRAUMEC Intersomatic Spacing Device of Diskal Substitution, should always be used together with Implant System for Column Fixation - TRAUMEC (**not object of this registration**), or together with other Spine Fixation System, at the surgeon's discretion, and such a choice is under his/her responsibility.

Table 1: Presentation of TRAUMEC Intersomatic Spacing Devices of Diskal Substitution

ITEM	CODE	DESCRIPTION	PICTURE
01	PA 01 01 0075	Mono Portal Lumbar Intersomatic Spacer 30x07mm	
02	PA 01 01 0076	Mono Portal Lumbar Intersomatic Spacer 30x08mm	
03	PA 01 01 0077	Mono Portal Lumbar Intersomatic Spacer 30x09mm	
04	PA 01 01 0078	Mono Portal Lumbar Intersomatic Spacer 30x10mm	

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05	PA 01 01 0079	Mono Portal Lumbar Intersomatic Spacer 30x11mm	
06	PA 01 01 0080	Mono Portal Lumbar Intersomatic Spacer 30x12mm	
07	PA 01 01 0081	Mono Portal Lumbar Intersomatic Spacer 30x13mm	
08	PA 01 01 0082	Inclined Mono Portal Lumbar Intersomatic Spacer 30x07mm	
09	PA 01 01 0083	Inclined Mono Portal Lumbar Intersomatic Spacer 30x08mm	
10	PA 01 01 0084	Inclined Mono Portal Lumbar Intersomatic Spacer 30x09mm	
11	PA 01 01 0085	Inclined Mono Portal Lumbar Intersomatic Spacer 30x10mm	
12	PA 01 01 0086	Inclined Mono Portal Lumbar Intersomatic Spacer 30x11mm	
13	PA 01 01 0087	Inclined Mono Portal Lumbar Intersomatic Spacer 30x12mm	
14	PA 01 01 0088	Inclined Mono Portal Lumbar Intersomatic Spacer 30x13mm	

IMPORTANT

For placing TRAUMEC Intersomatic Spacing Device of Diskal Substitution it is necessary the use of specific instruments (Table 02).

The Instrument Kit for placement of TRAUMEC Intersomatic Spacing Device of Diskal Substitution is registered with ANVISA under number **80455630005**, and neither **is part of this product nor of this registration process.**

Table 2 - List of instruments used for the implantation of TRAUMEC Intersomatic Spacing Device of Diskal Substitution.

ITEM	CODE	DESCRIPTION
01	PA.02.01.0031	Proof case for inclined and rectangular parallel lumbar intersomatic spacer
02	PA.02.01.0032	Case for parallel lumbar intersomatic spacer
03	PA.02.01.0033	Case for inclined lumbar intersomatic spacer
04	PA.02.01.0035	Lumbar intersomatic spacer introductory driver

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05	PA.02.01.0036	Grafting Impactor
06	PA.02.01.0034	Base for grafting impacting
07	PA.02.01.0011	Quick T coupling cable
08	PA.02.01.0037	Root flat retractor
09	PA.01.01.0038	Curved root retractor
10	PA.01.01.0039	Lumbar intersomatic spacer impact wrench
11	PA.01.01.0040	Spine Spacer 07mm
12	PA.01.01.0041	Spine Spacer 08mm
13	PA.01.01.0042	Spine Spacer 09mm
14	PA.01.01.0043	Spine Spacer 10mm
15	PA.01.01.0044	Spine Spacer 11mm
16	PA.02.01.0045	Spine Spacer 12mm
17	PA.02.01.0046	Spine Spacer 13mm
18	PA.02.01.0047	Curette
19	PA.02.01.0048	Vertebrae distracting tweezers

20	PA.02.01.0049	Articulated vertebrae distracting tweezers
21	PA.02.01.0001	Compressor tweezers
22	PA.02.01.0002	Distracting tweezers
23	PA.02.01.0003	Rod modeler
24	PA.02.01.0004	Torque wrench
25	PA.02.01.0005	Hammer
26	PA.02.01.0013	Counter-torque wrench
27	PA.02.01.0009	Rod twister
28	PA.02.01.0008	Left rod twister
29	PA.02.01.0007	Right rod twister
30	PA.02.01.0010	Rod holder clamp
31	PA.02.01.0006	Bone applicator
32	PA.02.01.0012	Straight quick coupling cable
33	PA.02.01.0011	Quick T coupling cable
34	PA.02.01.0030	Pedicle probe
35	PA.02.01.0029	Puncture
36	PA.02.01.0028	Space distractor driver
37	PA.02.01.0027	Rod depressor
38	PA.02.01.0026	Rupture driver
39	PA.02.01.0025	Male Ø 5,5mm
40	PA.02.01.0024	Male Ø 4,5mm
41	PA.02.01.0023	Bifida wrench
42	PA.02.01.0020	Initial guide driver polyaxial screw
43	PA.02.01.0019	Initial guide driver spondylolisthesis pedicle screw
44	PA.02.01.0018	Initial guide driver monoaxial pedicle screw
45	PA.02.01.0017	Hexa driver
46	PA.02.01.0016	Hexa driver 3,5mm
47	PA.02.01.0015	Hexa driver 2,5mm
48	PA.02.01.0014	Probe
49	PA.02.01.0021	Right pedicle marker
50	PA.02.01.0022	Left Pedicle Marker

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51	PA.02.01.0050	Template 60mm
52	PA.02.01.0051	Template 100mm
53	PA.02.01.0052	Template 200mm
54	PA.02.01.0053	Proof 7mm lumbar intersomatic spacer
55	PA.02.01.0054	Proof 8mm lumbar intersomatic spacer
56	PA.02.01.0055	Proof 9mm lumbar intersomatic spacer
57	PA.02.01.0056	Proof 10 mm lumbar intersomatic spacer
58	PA.02.01.0057	Proof 11 mm lumbar intersomatic spacer
59	PA.02.01.0058	Proof 12 mm lumbar intersomatic spacer
60	PA.02.01.0059	Proof 13 mm lumbar intersomatic spacer
61	PA.02.01.0060	Transporter tweezers

ITEM	CODE	DESCRIPTION
62	PA.02.01.0061	Lumbar intersomatic spacer introductory driver mono portal
63	PA.02.01.0062	Base for grafting impacting – mono portal
64	PA.02.01.0063	Grafting Impactor – mono portal
65	PA.02.01.0064	Lumbar intersomatic spacer impact wrench mono portal 01
66	PA.02.01.0065	Lumbar intersomatic spacer impact wrench mono portal 02
67	PA.02.01.0066	Lumbar intersomatic spacer impact wrench mono portal 03
68	PA.02.01.0067	Lumbar intersomatic spacer impact wrench mono portal 04
69	PA.02.01.0068	Proof 7mm mono portal lumbar intersomatic spacer
70	PA.02.01.0069	Proof 8mm mono portal lumbar intersomatic spacer
71	PA.02.01.0070	Proof 9mm mono portal lumbar intersomatic spacer
72	PA.02.01.0071	Proof 10mm mono portal lumbar intersomatic spacer
73	PA.02.01.0072	Proof 11mm mono portal lumbar intersomatic spacer
74	PA.02.01.0073	Proof 12mm mono portal lumbar intersomatic spacer
75	PA.02.01.0074	Proof 12mm mono portal lumbar intersomatic spacer
76	PA.02.01.0075	Grafting Impact Plier mono portal
77	PA.02.01.0076	Proof case for mono portal lumbar intersomatic spacer
78	PA.02.01.0077	Case for mono portal lumbar intersomatic spacer
79	PA.02.01.0078	Case for inclined mono portal lumbar intersomatic spacer

Composition:

Traumec Intersomatic Spacing Devices of Diskal Substitution are made in alloy Ti6AL4V as per norms specifications ASTM F136.

The Titanium has a combination of high mechanical resistance, high resistance to electrochemical corrosion and favorable biologic response, which makes it the most used metal as biomaterial. Among the titanium alloys, the alloy Ti-6Al-4V (ASTM F136) is the most used in several biomedical applications. The titanium is a special metal among light metals as aluminum and magnesium for their high rate resistance/weight. A contribution to

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the titanium biocompatibility is a big resistance to corrosion that is provided by its oxide, which forms a continuous and adherent film. Other contribution is its high dielectric constant when compared with the others oxides. The TiO provides Van der Waals strengths greater 2 than the other oxides, presenting, therefore, catalytic properties in several chemical reactions.

The titanium implants have about 45% less density than the ones have ion and cobalt in their compositions, an important factor related to the patient comfort, mainly in long bones fractures. Its low modulus of elasticity is another advantage since it minimizes the backpressure protection, and that is transferred to the bone. This relative importance backpressure is increased as the implant size increases. The titanium is extremely insoluble and acts as an inert material that does not interact with the organism (unlike stainless steel).

Ancillary Components

Spine Fixation System – Traumec (**not object of this register. Anvisa registration number 80455630041)** as any other spine fixation system, in the surgeon's discretion, and such a choice is under his/her responsibility.

Bone graft: the implants may be filled with any bone graft, and such a choice is under his/her responsibility. This graft starts a spacing inter somatic of Diskal Substitution device – Traumec, forming a solid bone (merger) that gets to fix the vertebra. This process is known as intervertebral merger. **(Not object of this register and not part of this product).**

Indication, purpose and use intended the medical product, as indicated by manufacturer

INDICATIONS FOR USAGE

We recommend Traumec intersomatic Spacing Devices of Diskal Substitution for intersomatic lumbar arthrodesis via posterior in case of trauma, fracture, and degenerative diseases; restoring and providing a maintenance of the inter height together with the Implant System to Spine Fixation – Traumec (not this register object) - or together with any other

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Spine Fixation System bone or synthetic, which will be used in the spacers cavities with the ultimate goal the upper and lower bone plateau calcification graft, where the spacer will be placed. The use of these ancillaries will be at the surgeon's discretion, and such a choice is under his/her responsibility.

Precautions, restrictions, warnings, special care and clarifications about medical product use, as well as storage and transportation.

USE INSTRUCTIONS

- Attention: implants provided non-sterile – sterilize them as per following recommended instructions:
- The surgical techniques vary accordingly to the surgeon's choice; it is his or her responsibility to the final choice of the method, type and dimension of the products to be used, just as the evaluation criteria of the surgery results.

Traumec Intersomatic Spacing devices of Diskal Substitution should be handled exclusively at proper environment and with the due care (should only be handled with sterilized gloves). Only qualified professionals should handle and implement Traumec Intersomatic Spacing devices of Diskal Substitution. The Traumec Intersomatic Spacing devices of Diskal Substitution should be used and adapted as per requirements and proper surgical techniques.

- Based on tests conducted, the doctor should consider the implementation levels. The degree of activity and the patient's conditions may have impact to the implant performance. The fact that no implant is as strong as the natural bone should be considered and, therefore, have limitations regarding biomechanical demands. The resistance limits of The Traumec Intersomatic Spacing devices of Diskal Substitution should be observed. Subject limits are described in the table below:

Static			Dynamic	
Compression	Shearing	Torsion	Subsistence testing	Compression Fatigue

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Maximum Force (N)	Maximum Force (N)	Angular Deformation º	Maximum Moment (Nm)	Maximum Load (Nm)	Load (Kgf)	Cycles
100286 (dp: 0,067%)	29504 (dp: 0,158%)	16,72 (dp: 11,96%)	240,36 (dp: 1,83%)	1538,84 (dp: 1,18%)	1000	5 million

CONTRAINDICATIONS

Active Infections.

- Patients who do not want or cannot follow the postoperative instructions due to the conditions that present (mental and physically).
- Foreign body sensibility. When there is a sensibility to the material suspect, the proper test should be done to exclude this possibility before the surgical act.

Blood flow limitations and/or previous infections that may slow down the cicatrisation and increase the infection possibility and/or implants rejection.

- Metabolic or systemic disorders or medical treatment that lead to gradual bone deterioration (corticosteroid therapy, immunosuppressive therapy).
- Conditions that, singularly or concomitantly, tend to impose severe loads over the fixation place, such as, but not limited to obesity, heavy services, active athletes, fall historic, alcoholism, smoking or drugs.
- Inappropriate coverage with healthy tissue.
- Pregnancy.
- Osteoporosis.

Observation: for the cases of Osteopenia when the bone mass is from 10% to 25% lower than the one considered normal, there is no use restriction, above this percentage is classified as osteoporosis, as per World Health Organization (WHO) becoming contraindicated.

WARNINGS AND PRECAUTIONS

The surgeon should be familiarized with Surgical Protocol for this device, previously to its use.

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- It is strictly forbidden the Traumec Intersomatic Spacing Devices of Diskal Substitution use separately, because it is imperative the ancillaries components use.
- The Traumec Intersomatic Spacing devices of Diskal Substitution in the smaller or bigger dimensions than the ones advocated to be used at the surgical act should be available.

The Traumec Intersomatic Spacing devices of Diskal Substitution correct selection and positioning and their ancillaries components; screws, rods and hooks is essential to optimize the bone fixation. The image or x-ray intensifier should be used to confirm the correct position in the medial and anterior-posterior plans.

- The fixation place immobilization should be kept until the arthrodesis be consolidated, confirmed by clinical exams and radiographic evaluations.

ADVERSE EFFECTS

- Tissue reactions: macrophagic reactions and foreign-bodies reactions to adjacent tissues.
- Condolisis.
- Heterotopic bone formation.
- Release or migration due to poor fixation in surgical procedure.

- Vascular alterations (avascular necrosis or bone termonecrosis).
- Cardiovascular disorders: bruises, thromboembolic disease, including vein thrombosis, pulmonary embolism and heart attack.
- Allergic reaction or sensibility to the implanted device.
- Peripheral neuropathy: nerves subclinical injuries, due to a clinical trauma.
- The system components rupture or deformation when requested beyond the established limits.
- Pain, discomfort and/or abnormal sensation due to the presence of The Traumec Intersomatic Devices of Diskal Substitution components.

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- Superficial and/or deep infection.

Growth restriction.

- Heterotopic bone formation.

SPECIAL CARES AND CLARIFICATIONS ABOUT THE PRODUCT USE

- NEVER reuse an implant, and the explanted ones should never be implanted again. The stress may lead to microscopic imperfections development, and, even the implant seems intact, its failure may occur.

- During the implantable device handling, there is always the risk that foreign and particulate materials, including gloves talc, materials Lint and cleaning agents and other surface contaminants may contact the device. Every effort should be made to limit the implants handling.

• If the patient is involved in any activity or occupation that may cause Implant stress (substantial walking, running, weight lifting or Muscle tension), these forces can cause device failure.

• Patients should be instructed in details about the implants limitations, including but not limited to the excess weight impact, either by their weight, or by their activity. The patient should understand that the implant is not as strong as natural and healthy the bone, and it can be broken if there is excessive demand. A patient who is unable to assimilate this information is at serious risk during the rehabilitation process.

• These devices durability is affected by biological, biomechanical and extrinsic factors, which limit its useful life. Therefore, the strict obedience to the indications, contraindications and precautions for this product are essential to maximize its useful life.

INFORMATION TO BE PROVIDED TO THE PATIENT (The patient should be guided by the doctor on the need of).

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• periodic medical follow-up, in order to observe possible durability the implant state and the adjacent bone changes. Only medical follow-up may detect possible components release or osteolisis occurrence;

• external supports use, walking aids and orthopedic appliances designed to immobilize the affected area and limit the load;

• awareness of the fact that the product does not replace and does not have the same performance of normal bone and, therefore, can break, deform or loosen as a result of excessive effort or activity.

• notification to the competent sanitary body, in case of adverse events and / or technical complaints associated with the device.

• For the purpose of traceability, the patient should be informed about the batch number, the product description, ANVISA registration and the product manufacturer's name. Such awareness will be given by the delivery of one label that is provided to the doctor to the patient, who should be guided about the implant traceability importance after its implantation.

DECONTAMINATION, CLEANING AND STERILIZATION

The Traumec Intersomatic Devices of Diskal Substitution are provided non-sterile and should be sterilized prior to use. Traumec recommends the sterilization and cleaning methods described below:

All metal implants should be thoroughly decontaminated, and cleaned before sterilization. They should be washed manually or in cleaning appliances using bactericidal and antifungal products. Prior to use, any cleaning agent must undergo oxidation tests. Aggressive cleaning agents such as acidic (sulfuric, nitric) mineral agents that may cause damages to the devices and particularly to the instruments should not be used.

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Do not use metal brushes, cleaners, and abrasives products. The device must be carefully rinsed after cleaning. Rinse thoroughly with water, 70% at 80% aqueous ethanol or isopropanol with subsequent ultrasonic treatment, or photolytic enzyme, or 1:100 sodium hypochlorite solution. If the water used contains a high concentration of ions, distilled water should be used. Dry the device immediately after cleaning.

The appropriate parameters of the sterilization processes (physical or chemical) for each equipment and volume, should be analyzed and conducted by people trained and specialized in sterilization processes, ensuring the complete efficiency of this procedure. For this, the manufacturer's instructions and methods must be followed according to internal guidelines of the hospital use.

The selected sterilization process must, in any case, comply with the EN556-1, which establishes that the theoretical probability of the presence of vital microorganisms be a maximum of 10-6 (S.A.L. [Sterility Assurance Level] – level = 10-6). It is the sole responsibility of the user to guarantee the use of an appropriate sterilization process and the sterility verification of all devices at any stage of the process.

It is recommended that the following parameters of the physical sterilization in autoclaves (saturated steam):

Cycle	Temperature	Exposure Time
Conventional (1 atm of pressure)	121 ºC	30 minutes
Conventional (1 atm of pressure)	132 ºC	15 minutes
Gravity	132 ºC	45 minutes
High Vacuum	132 ºC	4 minutes

NOTE: The time should only be marked when the heat of the sterilization chamber reaches the desired temperature.

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For cleaning, sterilization and general care of the instruments, we recommend Standard ASTM F 1744.

HANDLING CARE AND MEDICAL PRODUCT TRANSPORTATION

It is recommended that The Traumec Intersomatic Devices of Diskal Substitution be unpacked and sterilized immediately prior to surgical procedure in order to preserve the surface finish intact and original configuration, and should be handled as little as possible, when in these conditions.

Any implant that has been dropped, scratched, notched, or has undergone any other damage should be discarded. However, the decision as to its suitability is always of the surgeon who uses it.

TRACEABILITY

In order to ensure the product traceability it is recommended that the surgeon responsible for the implant, notify the distributor about the following product data, regarding to the implanted product:

• Name of the Hospital Unit;

• Name of the Surgeon;

• Date of Surgery;

• Name of the patient who received the implant;

• Product code;

• Product Lot Number;

• Product registration number in ANVISA.

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In each package two additional labels are placed, one to be affixed to the patient's chart for the hospital internal control and one delivered to the patient.

See the topic "Information to be provided to the patient" and do it accordingly.

The Traumec Intersomatic Devices of Diskal Substitution receive laser marking containing the manufacturer's logo, the batch number and the acronym of the material used in the implant manufacture. If it is necessary to remove the implant from the patient, all information will remain in the product. The components location marking of the Spine Fixing System is described in the technical drawings of the products.

The surgeon in charge should be aware of the procedures for reporting of adverse events and diversion of quality of health products, so that this information may be reach the patient. The reporting of adverse events and / or technical complaints associated with the device used should be made through the competent sanity authority. See the topic "Information to be provided to the patient" and do it accordingly.

The doctor in charge may also use the National Notification System for Sanitary Surveillance - NOTIVISA on the web platform www.anvisa.gov.br to perform reports of adverse events (AEs) and technical complaints (QT) related to products under sanitary surveillance.

DISPOSAL OF THE DEVICE

• Implants removed from the inner carton and inserted into the surgical environment, even if they have not been implanted nor contaminated by other sources, should be treated as contaminated material as it occurs to explanted devices. These devices must be disabled for use before discard. We recommend that parts are sanded, warped, or cut for their destruction.

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• Explanted devices are considered hospital waste (potentially contaminants products), and so they should be treated as, according to the local health authority.

• According to Resolution RE No. 2605, of 11/08/06, implantable devices of any nature classified as being of single use are prohibited from being reprocessed.

COMPLAINT / CUSTOMER SERVICE

Any customer or user of this medical device who has questions or wants further clarifications about the services and/or products offered, may contact TRAUMEC TECNOLOGIA E IMPLANTES ORTOPÉDICOS LTDA, through the contact data contained in the instructions for use and product packaging labels.

In the event of any problems, which make the medical device unfit for use, the customer will send to the manufacture in the packaging which keeps the physical integrity of the medical product. Therefore, the packaging should contain all information necessary for the identification of the medical product: the handling conditions, the methods of cleaning and disinfection used, as well as the description and the batch number.

This instruction for use refers to all products under registration

Anvisa n. 80455630006

Technician Responsible: José Luiz Caritá - CREA-SP - 0685038754

Non-sterile product - Sterilize before use

Single use product - Prohibited reprocessing

STORE AND TRANSPORT THE PRODUCT IN CLEAN AND DRY PLACE, AWAY FROM HEAT PROTECTED FROM DIRECT SUN LIGHT, IN TEMPERATURE: +10 TO +40 ºC - RELATIVE HUMIDITY: 85% MAXIMUM.

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Warnings, precaution, special cares: see use instructions

Manufactured by: TRAUMEC Tecnologia e Implantes Ortopédicos Importação e Exportação Ltda

Address: Rua 1A JC, nº138, Jardim Centenário
City: Rio Claro | State of Sao Paulo | CEP-13503-510
CNPJ: 09.123.223 / 0001-10 – Made in Brazil

Customer Service - Phone / Fax: +55 19 3522-1177 E-mail:

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Rev.:02

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